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WaveLight®

510(k) Summary of Safety and Effectiveness – AURIGA Device

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

Submitter:	WaveLight Laser Technologie, AG Am Wolfsmantel 5 91058 Erlangen Germany
Contact Person:	Alexander Popp WaveLight Laser Technologie, AG Am Wolfsmantel 5 91058 Erlangen Germany
Summary Preparation Date:	November 8, 2004

2. **Names**

Device Name:	AURIGA
Classification Name:	Laser Instrument, Surgical Powered Product Code: GEX Panel: Dermatology and Plastic Surgery

3. **Predicate Devices**

The AURIGA laser system is substantially equivalent to the Dornier Medilas H, Lumenis Versapulse Powersuite, convergent Omnipulse 30 or Trimedyne Omnipulse.

4. **Device Description**

Device Description AURIGA :
The AURIGA is a pulsed solid-state Holmium YAG-Laser System with a wavelength of approx. 2080 nm. The system is suitable for interdisciplinary use in surgical procedures involving open and endoscopic (laparoscopic, hysteroscopic, bronchoscopic, gastroenteroscopic and colonoscopic) breaking up stones, cutting (f. e. strictures) , ablation, vaporization, excision, incision and coagulation of tissue in the specialties as Urology, Pulmonology, Arthroscopy, Gastroenteroology, Gynecology, ENT (f. e. DCR), Lithotripsy, Orthopedics, Discectomy and General Surgery.

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5. Indications for Use

The AURIGA Holmium Laser system is intended to be used in surgical procedures involving open and endoscopic (laparoscopic, hysteroscopic, bronchoscopic, gastroenteroscopic and colonoscopic) breaking up stones, cutting (f. e. strictures), ablation, vaporization, excision, incision and coagulation of tissue in the specialties as Urology, Pulmonology, Arthroscopy, Gastroenteroology, Gynecology, ENT (f. e. DCR), Lithotripsy, Orthopedics, Discectomy and General Surgery.

6. Performance Data

not presented

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2005

Wavelight Laser Technologie AG
c/o Mr. Jeffrey D. Rongero
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, North Carolina 27709

Re: K051399
Trade/Device Name: Auriga
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 15, 2005
Received: June 17, 2005

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510 (k) Indications for Use

Indications for Use

510(k) Number (if known): N/A K051399
Device Name: AURIGA

Indications for Use:

The AURIGA Holmium Laser system is intended to be used in surgical procedures involving open and endoscopic (laparoscopic, hysteroscopic, bronchoscopic, gastroenteroscopic and colonoscopic) breaking up stones, cutting (f. e. strictures), ablation, vaporization, excision, incision and coagulation of tissue in the specialties as Urology, Pulmonology, Arthroscopy, Gastroenteroology, Gynecology, ENT (f. e. DCR), Lithotripsy, Orthopedics, Discectomy and General Surgery.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___N/A___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(indication for use only

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K051399